K120335

MAY - 3 2012

BIONIX®

Corporate Office

5154 Enterprise Blvd., Toledo, Ohio 43612

May 3, 2012

The following 510(k) summary has been prepared pursuant to requirements specified in 21CFR 807.92

1. **Submitter Information:**

   a. Applicant: Bionix Development Corporation
   5154 Enterprise Blvd.
   Toledo, Ohio 43612

   b. Contact: James Huttner M.D., Ph.D.
   Vice President, New Product Development
   Phone: (419) 727-8421
   Fax: (419) 727-4430
   Email: jhuttner@bionix.com

2. **Device Name:**

   a. Trade Name: Embrace Thermoplastic

   b. Common Name: Thermoplastic (moldable)

   c. Classification Name: Accessory to Accelerator, Linear, Medical
   (Per CFR section 892.5050)

3. **Intended Use:**

Embrace Thermoplastic from Bionix Development Corporation is intended to be used for the external support and immobilization of patients undergoing or receiving a course of external beam radiation therapy for the treatment of cancer and other diseases.

4. **Substantial Equivalence Device(s):**

Embrace Thermoplastic from Bionix Development Corporation is similar in composition, design and function to the following moldable low-temperature thermoplastics currently in use as accessories to radiation therapy systems, and used to support and immobilize a patient in a fashion that assists in reproducible positioning of that patient when receiving a course of external beam radiation therapy for the treatment of cancer or other medical conditions:

a. Klarity Thermoplastic manufactured and legally marketed by Larson Products, Inc., Columbus, Ohio. This device is listed under regulation number 892.5050, Accessory, Accelerator, Linear, Medical, and is classified as a Class II device. This device has been cleared by the FDA under K022708.

b. Aquaplast Thermoplastic manufactured and legally marketed by WFR/Aquaplast Corporation, Avondale, Pennsylvania. This device is listed under regulation number 892.5050, Accessory, Accelerator, Linear, Medical, and is classified as a Class II device. This device has been cleared by the FDA under K935067.

5. **Device Description:**

Embrace Thermoplastic from Bionix Development Corporation is a moldable low-temperature thermoplastic comprised of polycaprolactone, a biodegradable thermoplastic polymer that has been approved by the Food and Drug Administration for other medical device applications.

Embrace Thermoplastic becomes pliable and moldable by hand at temperatures of about 160 to 170 degrees Fahrenheit. This heating is most often done by immersion in hot water. To improve the ease of handling the polycaprolactone material in its heated, softened state, the Embrace Thermoplastic sheets will be bonded to a non-low temperature rigid thermoplastic frame. These frames also serve as convenient points to affix the Embrace Thermoplastic to an underlying patient support device.

Embrace Thermoplastic will be supplied in a variety of configurations and sizes, depending on the size and location of the body part to be immobilized, and to enable compatibility with other radiation therapy immobilization devices already in use. The Embrace Thermoplastic sheets may be perforated to enhance an even stretch over anatomical protuberances such as the nose and chin. This improves the conformity and rigidity of the resulting mask by preventing over-stretching and thinning in these areas. Perforation patterns may be uniform (as in a sheet intended to be used over a limb) or variable (such as in a sheet intended to be used with the head), all designed to enhance the even stretch of the material and the rigidity of the resultant mask.

The typical application of Embrace Thermoplastic is to create a conformal "mask" of an anatomical body part, such as the head, by stretching the pliable heated polycaprolactone sheet over the body part and allowing it to cool and become rigid. The resulting

conformal "mask" can then be used to position and reposition a patient undergoing a course of external beam radiation therapy with a high degree of accuracy and reproducibility.

6. Comparison to Predicate Devices:

The following table summarizes the comparison of Bionix Development Corporation Embrace Thermoplastic to predicate devices:

Attribute	Klarity Thermoplastic (Larson Products)		Aquaplast Thermoplastic (WFR/Aquaplast)		Embrace Thermoplastic (Bionix)	
Intended Use	Support and immobilize patients receiving external beam radiation therapy		Support and immobilize patients receiving external beam radiation therapy		Support and immobilize patients receiving external beam radiation therapy	
Composition	Polycaprolactone		Polycaprolactone		Polycaprolactone	
Melting Temperature	160 - 170 degrees F		160 - 170 degrees F		160 - 170 degrees F	
Rigidity	1.388 lbs/in^2		3.459 lbs/in^2		1.080 lbs/in^2	
Shrinkage	1.9 %		1.5 %		1.1 %	
Features	Available as perforated and non-perforated sheets		Available as perforated and non-perforated sheets		Available as perforated and non-perforated sheets	
Sheet Thickness	2.4 mm and 3.2 mm		2.4 mm and 3.2 mm		2.4 mm and 3.2 mm	
Non-Low Temperature Thermoplastic Frame (for handling)	Yes		Yes		Yes	
Attaches to Patient Support Device	Yes		Yes		Yes	
Radiolucency	@0 degrees	@ 45 degrees	@0 degrees	@ 45 degrees	@0 degrees	@ 45 degrees
• 6 MeV	0.9844	0.9783	0.9915	0.9872	0.9888	0.9827
• 10 MeV	0.9880	0.9855	0.9935	0.9906	0.9885	0.9891
• 18 MeV	0.9914	0.9868	0.9949	0.9924	0.9934	0.9904

7. Bench Testing:

Samples of Embrace Thermoplastic (Bionix Development Corporation), Klarity Thermoplastic (Larson Products) and Aquaplast Thermoplastic (WFR/Aquaplast Corporation) were tested for radiation attenuation using medium energy (6 MeV (6x)), and high energy (10 MeV (10x) and 23 MeV (23x)) x-ray beams. The x-ray beams were delivered at two gantry angles, 0 degrees (G0) and 45 degrees (G45).

Radiation attenuation for the Embrace Thermoplastic at 6 MeV and 10 MeV was less than 2% and that at 18 MeV less than 1%, for gantry angles at both zero and 45 degrees. These data are comparable to the Aquaplast Thermoplastic and the Klarity Thermoplastic samples tested. This testing confirms the Embrace Thermoplastic is substantially equivalent to the predicate devices for radiation attenuation.

Further bench testing was performed to compare the physical characteristics and actual handling properties of Embrace Thermoplastic (Bionix Development Corporation) to Klarity Thermoplastic (Larson Products) and Aquaplast Thermoplastic (WFR/Aquaplast Corporation). This data is summarized in the following table. It can be seen from this evaluation that the material and handling characteristics and physical properties of the Embrace Thermoplastic are comparable to the properties of the predicate thermoplastic materials.

Manufacturer	Material Tested	Measured Thickness (mm)	Mfr Recommended Melting Temp. (° F)	Mfr Recommended Heating Time (Minutes)	Time To Transparency (Seconds)	Mfr Recommended Cooling Time (Minutes)	Available Forming time (Seconds)	Rigidity (lbs/square inch)	Percent Shrinkage (24 Hrs)
WFR/Aquaplast	3.2 mm Aquaplast	3.54	165	4	41	5	50	3.459	1.5%
Larson Products	3.2 mm Klarity	3.2	165	2	60	5	29	1.388	1.9%
Bionix	3.2 mm BDC Thor	3.2	160	2	49	5	54	1.080	1.1%

8. Clinical Testing:

No clinical testing was performed on the Embrace Thermoplastic material from Bionix Development Corporation.

9. Conclusion:

The similarity of design, features, composition, and performance indicate that Embrace Thermoplastic from Bionix Development Corporation will perform as well as the legally marketed Klarity Thermoplastic from Larson Products, Inc. and the legally marketed Aquaplast Thermoplastic from WFR/Aquaplast Corporation for the intended use of

external support and immobilization of patients undergoing or receiving a course of external beam radiation therapy for the treatment of cancer and other diseases.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

MAY - 3 2012

James Huttner M.D., Ph.D.
Vice President, New Product Development
Bionix Development Corporation
5154 Enterprise Blvd.
TOLEDO OH 43612

Re: K120335
Trade/Device Name: Bionix Thermoplastic
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: IYE
Dated: February 1, 2012
Received: February 8, 2012

Dear Dr. Huttner:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement:

510(k) Number (if known): (Not Known) K120335
Device Name: Bionix Thermoplastic
Indications for Use:

Silhouette Thermoplastic from Bionix Development Corporation is intended to be used for the external support and immobilization of patients undergoing or receiving a course of external beam radiation therapy for the treatment of cancer and other diseases.
It is intended to be used by or under the direction of a licensed physician.

Prescription Use __X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

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(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety
510k K120335